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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,346	04/15/2005	Stefan Frahling	GIL-16027	8225
7609 7590 11/06/2008 RANKIN, HILL & CLARK LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
11/06/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,346

Applicant(s)

FRAHLING ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 10 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 10 and 15-22 is/are rejected.
- 7) ☒ Claim(s) 10, 15, 16, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 19 June 2008.

The Examiner acknowledges the following:

Applicants continuity of priority has been verified via the documents submitted. The Examiner thanks Applicants for pointing out the incorrectly applied time requirement. Applicants are granted priority to DE 103 17 982.8, filed 17 April 2003, and DE 102 48 314.0, filed 16 October 2002.

Claims 1, 4-6 and 10 have been amended and claims 15-22 have been added. Support for the amendments, while not expressly provided, was found either within Applicants' disclosure and/or originally filed claims.

Claims 2, 3 and 9 have been cancelled.

Thus, claims 1, 4-6, 10 and 15-22 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to both the Title of the Invention render the objections to the Specification moot. Thus, said objections have been **withdrawn**.

Objection to the Claims

Applicants' cancellation of claims 2 and 3, and amendment to claim 10, render the objections to claims 2, 3 and 10, moot. Thus, said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendment to claim 1 regarding the preamble, "and/or" and "optionally" renders the rejection to claims 1 and 4-6, under 35 USC 112, second paragraph, moot. Thus, said rejections have been **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' amendments to claim 1 render the rejection to claims 1, 4, 5 and 10 under 35 USC 102(b) as being anticipated by Dogliani (EP 0 888 769), moot. Thus, said rejection has been **withdrawn**.

Applicants' amendments to claim 1 render the rejection to claims 1, 6 and 10 under 35 USC 102(b) as being anticipated by Wunderlich et al. (USPN 5,578,307), moot. Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 103(a)

Applicants' amendments to claim 1 render the rejection to claims 1, 4-6 and 10 under 35 USC 103(a) as being unpatentable over Dogliani in view of Wunderlich, moot. Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 25 February 2008:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Similar to claim 1, dependent claim 10 recites "and/or" within its limitations with regards to the aqueous solution of one or more active substances and/or auxiliary substances. It is not clear which limitations are part of the invention.

RESPONSE TO ARGUMENTS

Applicants' remarks with regard to the rejection of claim 10 under 35 USC 112, second paragraph, as being indefinite have been fully considered, but are not persuasive.

Applicants discuss amendments made to claim 1, but do not direct any of their remarks to the amending claim 10; the claim is only amended to recite "comprising one or more active substances and/or auxiliary substances". Applicants further allege that the forgoing amendments (i.e. to claim 1) clarify the minimum composition of the material applied to the external skin.

In response, the Examiner respectfully disagrees with the latter of Applicants' allegations and submits that the amended claim still does not set forth the minimal compositional requirements for the applied article.

Thus, for these reasons, Applicants' amendment and remark regarding the claim are found unpersuasive. The above rejection is hereby maintained.

NEW REJECTIONS

In light of Applicants' amendments, most notably to claim 1, the following rejections have been newly added:

SPECIFICATION

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "scaffold-forming agent". The Examiner has further searched the specification and notes that Applicants use the term "skeleton-forming agent" throughout the disclosure. Herein, and for the purpose of examination on the merits, the term "scaffold-forming agent" will be interpreted to recite "skeleton-forming agent".

Claim Objections

Claims 10 and 21, as amended, and new claims 15, 16 and 22, are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place

the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation recited with claim 10, wherein “the shaped article is contacted with an aqueous solution comprising one or more active substances and/or auxiliary substances” is deemed by the Examiner to be a limitation which is broader in scope compared to the “contacting the shaped article with water limitation”, which is recited in claim 1. Claims 15 and 16 are objected to since they depend from claim 10. Herein, and for the purposes of examination on the merits, the Examiner interprets the limitations of claims 10 and 21, and thus claims 15, 16 and 22, as reciting the limitation “contacting the shaped article with water”.

CLAIM REJECTIONS - 35 USC § 103

Claims 1, 4-6, 10 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagashima et al. (USPN 6,269,817).

The instant claim 1 is directed to a method of using a shaped article to apply at least one scaffold-forming agent to an external skin or hair surface of a human or animal comprising (1) providing a sized and shaped article, free of protein-based scaffolding agent, (2) disintegrate said article with water to form a solution or a gel, and (3) applying the composition to the intended surface. With regard to the limitations recited in claim 1, which state that the shaped article has been “molded [and] freeze-dried”; said limitations are deemed by the Examiner as reciting product-by-process limitations, which per MPEP §2113 hold no patentable weight. The scaffolding agent recited in claim 1, is further recited as comprising at least one polysaccharide such as sodium alginate (claims 4 and 5). Claim 6 recites the article as sphere-shaped prior to contact with water (claim 6). Claims 10, 15, 16, 21 and 22, as discussed above, are interpreted as

reciting contacting the article with water. The shaped article is recited as further comprising one or more cosmetic or pharmaceutically active substances (claims 17 and 18) or one or more auxiliary substances such as squalene (claims 17, 19 and 20).

Nagashima et al. teach a cosmetic method for washing skin with a cleanser wherein said cosmetic method comprises administering a massage with a massaging cosmetic comprising disintegrating particles disintegrating particles before the skin care cosmetic is used (claims 8 and 9). It is further taught that when the practiced cosmetic is used for massaging in the treatment method said cosmetic may be in the solid form, but is preferably in liquid form. Such preferred liquid forms includes gels, crèmes and pastes (col. 11, line 62 to col. 12, line 3). Primary particles of the composition are taught as being spherical in shape (col. 7, lines 55-56) and as having a diameter ranging from 100-1000 microns (0.1-1 mm) as well as possibly greater than 1000 microns (col. 8, lines 27-30 and lines 57-60). Disintegrating microcapsules are taught as comprising one or more capsule materials such as sodium alginate (col. 8, lines 31-52). Cosmetic compounds included in the composition include skin enhancing oils such as squalane (col. 10, lines 12-18 and lines 25-29). Auxiliary substances used in the composition, in addition to those already mentioned, include cosmetic adjuvants such as surfactants, dyes and pharmacological components (col. 12, lines 1-8).

Nagashima et al. do not expressly teach (1) the volumetric limitations of the article, (2) or the use of water as recited in steps (a) and (b), respectively, of claim 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a protein-free composition comprising scaffold-forming agent, squalene and

additional cosmetic substances, in the presence of water, as suggested by Nagashima, modify the size of the article to be used, and use said article to apply said agent to an epidermal surface of a person or animal.

One of ordinary skill in the art would have been motivated to do this because Nagashima expressly teaches, as discussed above, the incorporation of the instantly claimed scaffold-forming agent (e.g. sodium alginate) into solid, sphere-shaped cosmetic particles in combination with skin-enhancing components such as squalane, in addition to other cosmetic and pharmacologically active substances. Furthermore, the disintegration of particles prior to use (claims 8 and 9) is not expressly taught as being accomplished with water. However, given that the formulations of the practiced invention comprise or may comprise a high percentage of water it follows that one of ordinary skill in the art would have been highly motivated to use water convert the solid form of the composition to the liquid or gel form (col. 12, line 62 to col. 13, line 3) prior to applying the composition as instantly claimed.

Regarding the initial article size and shape prior to hydration in step (b) of claim 1, since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be *prima facie* obvious for a person of ordinary skill in the art to employ, absent any showing of criticality (see MPEP §2144.04 (IV)(A.) and (B.)). Thus, it would have been customary for an artisan of ordinary skill, to vary size and shape of the claimed wettable cosmetic article prior to use, for any number of aesthetic reasons such as ease of handling or comfort. Thus, absent some

demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

All claims under consideration remain rejected; no claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615